

REMARKS

I. Amendments

By this amendment, Claims 1-16, 22 and 23 have been amended, claims 17-21 and 24-28 have been canceled without prejudice to the filing of further continuing applications and new claim 29 has been added.

Typographical and grammatical errors have also been corrected throughout the specification.

This amendment adds no new matter to the specification. Support for this amendment is found in the specification and claims as filed.

The Examiner included a handwritten note that hydrogens were missing from the structure at the top of page 43. While Applicants believe that one skilled in the art would understand hydrogens to be located on the nitrogen atom of the carbamates, they have added the nitrogens to the structure by this amendment to satisfy the Examiner.

Applicants also note that the elected species for the biologically active substance which the Examiner has indicated on page 2 of the Office Action is incorrect. The Examiner has included an extraneous Gly residue at the N-terminal end of the peptide. The elected species should be 5-oxo-Pro-His-Trp-Ser-Tyr-D-Leu-Leu-Arg-Pro-NH₂. Applicants respectfully request that the Examiner take note of this point.

No change of inventorship is necessitated by this amendment.

II. Discussion of the Amendments to the Specification

Applicants previously requested amendments to the specification to remedy typographical and grammatical errors, as well as to put the specification into conformance with U.S. practice. The Examiner has indicated that the previously requested changes had not been made, as they were not in the proper format. In this amendment, the changes are made in proper format. Entry is respectfully requested.

III. Discussion of the 35 U.S.C. Sec. 112, First Paragraph Rejection of Claim 22

Claim 22 has been rejected under 35 U.S.C. Sec. 112, first paragraph as allegedly non-enabled as to the terms "preventing" and "treating".

By this amendment, "preventing" has been deleted from claim 22.

Moreover, Applicants have made claim 22 a claim for a method of treating certain conditions, dependent upon claim 11. This amendment adds no new matter to the specification. Support for the amendment may be found at page 41, line 9 – page 42, line 24 *inter alia*.

LH-RH derivatives are understood by those skilled in the art to be effective for the treatment of hormone-dependent diseases. For example, WO 96/22786, a reference of record in the present application, lists several conditions which can be favorably affected on pages 5 and 6. Therefore, Applicants do not believe that the Examiner's conclusion that "While it is possible that some success has been achieved in the treatment of one or more of the foregoing disorders, there is no evidence of record that any of the recited disorders can be successfully treated." is correct.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 112, first paragraph rejection of claim 22.

IV. Discussion of the 35 U.S.C. Sec. 112, Second Paragraph Rejection

Claims 1-16 and 21-23 have been rejected under 35 U.S.C. Sec. 112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically the Office Action stated that 1) the term "substance" in claim 1 has been objected to; 2) all claims need capitalization of the first word in the claim; 3) the term "LH-RH" in claim 3 has been objected to; 4) in claim 6, the term "above" has been objected to; 5) claims 7 and 8 have been objected to as allegedly not properly sub-generic to claim 6; 6) the sequence ID number should be included in claim 11; 7) the phrase "per unit mass (gram)" is objected to in claim 12; 8) in claim 21, "a pharmaceutical" has been objected to; 9) claim 22 has been objected to for various reasons and 10) "the hydroxynaphthoate" in claim 23 has been objected to. Each aspect of the rejection will be discussed separately in the following paragraphs.

With respect to the first aspect of the rejection, substances are defined on page 6, lines 1-12. In deference to the Examiner's statement that "substance" is sufficiently broad to include salts thereof, Applicants have removed "or salt thereof" from claims 1 and 15.

With respect to the second aspect of the rejection, the first word of each claim has been capitalized by this amendment.

With respect to the third aspect of the rejection, the Applicants do not believe that it is necessary to fully write out the name of the abbreviation LH-RH the first time it appears in the claims, as this abbreviation is quite well-known and understood by scientists. Furthermore, the abbreviated version of the name appears in the claims of many U.S. patents such as U.S. Patent Nos. 6,503,534; 6,485,707; 6,448,031 and 6,319,192 without first appearing in the claims as the full name. Therefore, Applicants believe that the version "LH-RH" is acceptable in U.S. patent practice. Moreover, LH-RH has been defined in the specification at page 6, line 15, so there can be no doubt as to the meaning of the abbreviation.

With respect to the fourth aspect of the rejection, Applicants have deleted the superfluous "above" from claim 6.

With respect to the fifth aspect of the rejection, the Examiner believes that claims 7 and 8 are not properly sub-generic to claim 6. However, this is not the case. Lactic acid-glycolic acid polymers are defined in the specification at page 12, lines 6-24. According to the specification, and as is understood by those skilled in the art, homopolymers of either lactic acid or glycolic acid are included in the broadly defined "lactic acid-glycolic acid" polymers. Therefore, Applicants assert that claims 7 and 8 are properly sub-generic to claim 6.

With respect to the sixth aspect of the rejection, claim 11 has been modified to recite "SEQ ID NO.: 1".

With respect to the seventh aspect of the rejection, "per unit mass (gram)" has been deleted from claim 12.

With respect to the eighth aspect of the rejection, Applicants have cancelled claim 21 by this amendment.

With respect to the ninth aspect of the rejection, claim 22 has been modified to recite a method of treating certain conditions. This modification introduces no new matter to the specification as explained in Sec. III above. Furthermore, Applicants have split the "contraceptive" aspect of the invention into a separate new claim, claim 29, as the Examiner has suggested.

With respect to the tenth aspect of the rejection, claim 23 has been amended to recite "hydroxynaphthoic acid salt", in accordance with the specification at page 10, lines 30 and 31 *inter alia*.

Therefore, Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 112, second paragraph rejection.

V. Discussion of the 35 U.S.C. Sec. 102(a) Rejection over Kamei *et al.*

Claims 1-3, 5-16 and 21-23 have been rejected under 35 U.S.C. Sec. 102(a) as allegedly anticipated by Kamei *et al.*, WO 98/32423. Applicants respectfully traverse the rejection.

The hydroxynaphthoic acid component recited in claims 1 and 23 of the present application is not anticipated by the cited reference.

By this amendment, Applicants have amended claim 1 to delete "a" from "a hydroxynaphthoic acid". Applicants wish to also draw the Examiner's attention to the fact that hydroxynaphthoic acid is defined in the specification at page 9, lines 20-31. Under the definition provided, the teachings of Kamei *et al.* directed to 4,4'-methylenebis (3-hydroxynaphthoic acid) do not encompass the hydroxynaphthoic acids recited by Applicants. For this reason, the cited reference does not anticipate the aspects of Applicants' invention as set forth in claims 1 and 23 as amended.

Claims 2, 3, 5-16 and 22 depend upon claim 1. Claim 21 has been cancelled. Applicants submit that the more specific dependent claims are not anticipated by the cited reference for the same reason provided with respect to the independent claims.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 102(a) rejection over Kamei *et al.*

VI. Discussion of the 35 U.S.C. Sec. 103 Rejection of Claim 1 over Conrow *et al.*

Claim 1 has been rejected under 35 U.S.C. Sec. 103 as allegedly obvious in view of Conrow *et al.*, U.S. Patent No. 4,049,640. Applicants respectfully traverse the rejection.

The hydroxynaphthoic acid component recited in claim 1 of the present application is not rendered obvious by the cited reference.

By this amendment, Applicants have amended claim 1 to delete "a" from "a hydroxynaphthoic acid. Applicants wish to also draw the Examiner's attention to the fact that hydroxynaphthoic acid is defined in the specification at page 9, lines 20-31. Under the definition provided, the teachings of Conrow *et al.* directed to substituted bisnaphthylazodiphenyl ureido complement inhibitors do not encompass the hydroxynaphthoic acids recited by Applicants. For this reason, the cited reference does not teach or suggest the aspects of Applicants' invention as set forth in claim 1 as amended.

Therefore, Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 103 rejection over Conrow *et al.*

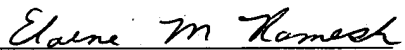
VII. Conclusion

Reconsideration of the pending claims in view of the amendments and arguments presented above is requested. Should the Examiner believe that a conference with Applicants' Attorney would advance prosecution of this application, he is respectfully invited to call Applicants' Attorney at the number below.

Respectfully submitted,

Dated: February 7, 2003

(847) 383-3391
(847) 383-3372


Elaine M. Ramesh, Ph.D., Reg. No. 43,032
Mark Chao, Ph.D., Reg. No. 37,293

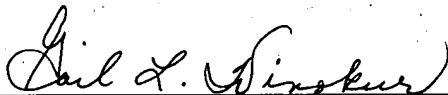
Attorney for Applicants
Customer No. 23115

Takeda Pharmaceuticals North America, Inc.
Intellectual Property Department
Suite 500, 475 Half Day Road
Lincolnshire, IL 60069 USA

Certificate of Mailing under 37 CFR 1.10

The undersigned hereby certifies that this document, along with any attachments, is being deposited in an envelope addressed to The Commissioner of Patents and Trademarks, with sufficient postage with the United States Postal Service EXPRESS MAIL Post Office to Addressee Service on this date February 7, 2003.

Express Mail Label No. EV 193976155 US



Printed Name: Gail L. Winokur